United States Court of Appeals for the Federal Circuit

C R BARD INC., BARD PERIPHERAL VASCULAR, INC.,
Plaintiffs-Appellants

v.

ANGIODYNAMICS, INC.,
Defendant-Appellee

2019-1756, 2019-1934

Appeals from the United States District Court for the District of Delaware in No. 1:15-cv-00218-JFB-SRF, Senior Judge Joseph F. Bataillon.

Decided: November 10, 2020

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by SETH W. LLOYD, BRIAN ROBERT MATSUI; VINCENT JOSEPH BELUSKO, DYLAN JAMES RAIFE, Los Angeles, CA.

DANIELLE VINCENTI TULLY, Cadwalader, Wickersham & Taft LLP, New York, NY, argued for defendant-appellee. Also represented by JACLYN HALL, CHRISTOPHER A. HUGHES, JOHN MOEHRINGER, MICHAEL BRIAN POWELL.

Before REYNA, SCHALL, and STOLL, *Circuit Judges*.

REYNA, *Circuit Judge*.

The appellants, manufacturers of implantable medical devices for intravascular injections, sued their competitor for patent infringement. Partway through the jury trial, the district court granted judgment that the asserted claims were not infringed, were not willfully infringed, and were invalid as directed to printed matter. We hold that there was substantial evidence in the record to support a jury finding of infringement and willfulness. We also hold that the asserted claims are not directed solely to printed matter, and thus are patent eligible under 35 U.S.C. § 101, and that a genuine dispute of material fact precludes summary judgment as to anticipation. Thus, we reverse-in-part and vacate-in-part the district court's judgments and remand for further proceedings.

BACKGROUND

A. The Technology, Patents, and Accused Products

The appellants, C. R. Bard Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"), and the appellee, AngioDynamics, Inc., are manufacturers of vascular access ports, which are devices implanted underneath a patient's skin that allow medical providers to inject fluid into the patient's veins on a regular basis without needing to start an intravenous line each time. Vascular access ports were traditionally used to administer injections at a low pressure and flow rate. However, certain procedures, like computed tomography ("CT") imaging, required injection of fluids into patients at a high pressure and high flow rate. This type of injection is referred to as "power injection." As of 2005, vascular access ports were not specifically approved by the FDA for use with power injection. Nonetheless, certain medical providers were using existing ports for power injection, and in some cases, the pressure of the injection ruptured the port, seriously injuring the patient. In light

of these reported cases, the FDA cautioned medical providers in 2004 and 2005 that they should not use vascular access ports for power injection unless the ports were specifically and identifiably labeled for such use. J.A. 31850–51, 32089.

At the time, Bard's commercially marketed vascular port product was already structurally suitable for power injection, although it had not been approved for such use. Around the time of the FDA warnings, Bard confirmed the power injection capability of its product and proceeded to develop identifiable features that would reliably convey that capability to medical providers after the port was implanted. The primary identifying feature Bard developed was a radiographic marker in the form of the letters "CT" etched in titanium foil on the device. This marker could be detected during an x-ray scan such as the "scout scan" typically performed at the start of a CT procedure. Other identifiers incorporated into the device included a triangular shape and small bumps that were palpable through the skin. Bard also included identifiers with its product that were separate from the device itself, such as labeling on the device packaging and small items to be carried by the patient or kept in the patient's medical records (i.e. a keychain, wristband, or sticker). Bard obtained FDA approval for its new product and launched it under the brand name, PowerPort, as the first vascular access port labeled for power injection.

Bard also filed patent applications claiming its strategies for identifying a power injectable port. These applications eventually issued as the patents-in-suit in this case, U.S. Patent Nos. 8,475,417, 8,545,460, and 8,805,478. The patents have substantially similar written descriptions, and each of the claims require the presence of a radiographic marker identifying the claimed port as power injectable.

The '417 and '460 patents claim "assemblies" and "systems" for identifying a vascular access port as suitable for power injection. Bard asserted claims 5, 6, 12, and 13 of the '417 patent, which each depend from either claim 1 or claim 8; and dependent claims 2 and 4 of the '460 patent, which depend from claim 1. Claim 1 of the '417 patent is illustrative of these claims:

> 1. An assembly for identifying a power injectable vascular access port, comprising:
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> a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;
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> a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;
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> a second identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the second feature identifying the access port as suitable for accommodating a pressure within the cavity of at least 35 psi, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and
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> a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

'417 patent col. 30 l. 51–col. 31 l. 6. The asserted dependent claims of the '417 and '460 patents further require that the radiographic marker be in the form of radiographic letters

or other symbols, patterns, or characters, and that the extrinsic identifier include one or more of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, or a label provided on the product packaging.

The '478 patent claims methods for performing a power injection procedure that include identifying a vascular access port suitable for power injections and performing the power injection. Bard asserted claims 3, 5, 9, and 11 of the '478 patent, which each depend from either claim 1 or claim 8. Claim 8 is illustrative of the method claims:

> 8. A method of performing a power injection procedure, comprising:
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> providing an access port including a cannula-impenetrable housing and a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port;
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> implanting the access port in a subcutaneous pocket formed under a patient's skin;
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> taking an image of the implanted access port via imaging technology;
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> identifying the access port as being suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port via the image of the radiographic feature of the access port; and
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> injecting contrast media fluid through the access port at a rate of at least 1 milliliter per second.

'478 patent col. 31 ll. 41–56. The asserted dependent claims of the '478 patent contain additional limitations concerning the radiographic feature and external features that are analogous to those in the asserted dependent claims of the '417 and '460 patents.

Not long after Bard obtained FDA approval for its PowerPort product, AngioDynamics sought and obtained FDA approval to market its own vascular access port products as suitable for power injection. While its initial power injection product did not include any features intrinsic to the device that identified its functionality, the company added identifiers such as a scalloped shape and a radiographic "CT" marker to its later products for easier identification. These new products were sold under the brand names Smart Port CP, Smart Port LP, Smart Port mini, Xcela, Xcela Plus, and BioFlo.

B. Procedural History

Bard sued AngioDynamics in the District of Delaware, asserting that AngioDynamics's power injectable vascular access port products infringed the '417, '460, and '478 patent claims. AngioDynamics moved to dismiss the complaint on the ground that all claims of the patents-in-suit were ineligible under § 101. The district court denied the motion as premature. *C. R. Bard, Inc. v. Angiodynamics, Inc.*, 156 F. Supp. 3d 540, 554 (D. Del. 2016). The parties later cross-moved for summary judgment on the questions of patent eligibility, novelty, and enablement. Judge Bataillon concluded that factual disputes remained on all issues and denied the motions without prejudice. *C R Bard, Inc. v. AngioDynamics Inc.*, No. 1:15CV218, 2018 WL 3130622, at *12–13 (D. Del. June 26, 2018)

In advance of trial, the court requested a report and recommendation from Magistrate Judge Fallon on certain remaining claim construction issues, including whether the "radiographic letters" and "visually perceptible information" limitations were entitled to patentable weight

under the printed matter doctrine.[1] Judge Fallon determined that these limitations were not entitled to patentable weight because they were directed to the content of information that was not "functionally or structurally related" to the claimed ports. *Bard Peripheral Vascular, Inc. v. AngioDynamics, Inc.*, No. CV 15-218-JFB-SRF, 2019 WL 1996022, at *3–6 (D. Del. Feb. 11, 2019). The district court adopted the recommendation.

The parties proceeded to trial. Bard presented its case on infringement, willfulness, and damages through live testimony from a named inventor, infringement expert Timothy Clark, M.D., and a damages expert, along with deposition testimony from AngioDynamics employees. At the close of Bard's case-in-chief, AngioDynamics moved for judgment as a matter of law ("JMOL") of non-infringement and no willfulness. In asserting non-infringement, AngioDynamics argued that (1) Dr. Clark's testimony could not create triable issues of fact because he had improperly interpreted the claims to require that the vascular access port be "intended" for use with power injection, contrary to the court's claim construction; (2) Bard had not conducted any testing to establish that AngioDynamics's Xcela product met the flow rate and pressure requirements of the asserted claims; and (3) there was no direct evidence that a single entity directly infringed the '478 patent's method claims. AngioDynamics also argued there was insufficient evidence of willful infringement because AngioDynamics had obtained invalidity opinions from counsel regarding

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[1] This followed our decision in *Praxair* that the questions of whether certain claim elements are directed to printed matter and whether such printed matter is functionally related to other claim elements may properly be resolved during claim construction. *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 890 F.3d 1024, 1033 (Fed. Cir. 2018).

the patents-in-suit and Bard had not shown that the opinions were deficient.

In response to AngioDynamics's JMOL motion, the court asked the parties, sua sponte, whether the issue of "patent eligibility and printed matter" was also ripe for decision. J.A. 25849. The parties disagreed on the question. The court terminated the trial, indicating that it would grant JMOL on willfulness and ineligibility.

The court issued a written opinion granting AngioDynamics's motion for JMOL of non-infringement and no willful infringement. *C R Bard Inc. v. AngioDynamics Inc.*, 382 F. Supp. 3d 332, 335 & n.5, 337, 341 (D. Del. 2019). In the same opinion, the court stated that the asserted claims were invalid because they were directed to printed matter as ineligible subject matter and were not inventive. *Id.* at 337–41. He followed this decision with an order "sustain[ing] AngioDynamics's oral motion for Judgment as a Matter of Law, as well as its motions for summary judgment under Federal Rule of Civil Procedure 56, on the grounds that the claims of the Asserted Patents are invalid, not patent-eligible, not infringed and not willfully infringed." J.A. 2.

Bard appeals the judgments of non-infringement, no willfulness, and invalidity, including ineligibility under § 101. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We first address the court's judgments on infringement and invalidity. Applying the law of the regional circuit—here, the Third Circuit—we review the district court's grant of JMOL and summary judgment *de novo*. *See Acumed v. Adv. Surgical Servs.*, 561 F.3d 199, 211 (3d Cir. 2009); *Facenda v. NFL Films, Inc.*, 542 F.3d 1007, 1013 (3d Cir. 2008). A court may grant JMOL during a jury trial only when (1) a party has been fully heard on an issue and (2) the court finds that a reasonable jury would not have a

legally sufficient evidentiary basis to find for the party on that issue. FED. R. CIV. P. 50. A court will grant summary judgment on a claim or defense when there is no genuine dispute as to any material fact and a party is entitled to judgment as a matter of law. FED. R. CIV. P. 56.

A. Infringement

The district court granted JMOL of non-infringement on each of the three grounds raised by AngioDynamics: (1) that Dr. Clark failed to apply the court's claim construction for the terms "vascular access port" and "access port" in rendering his opinion; (2) that Bard had not shown that the accused Xcela product met the flow rate requirements of the asserted claims because Bard had not tested the product and relied only on AngioDynamics's statements to the FDA regarding the product's capabilities; and (3) that Bard's evidence had not shown that a single entity performed all claim steps of the asserted method claims of the '478 patent. *Bard*, 382 F. Supp. 3d at 336–37. Bard challenges each of these grounds.

We agree with Bard that the district court erred in granting JMOL. First, although Dr. Clark testified during cross-examination that he believed there was an intent requirement "implied" in the court's construction of the "access port" terms as "structured for power injection," this mistake did not undermine the factual basis of his infringement opinion. J.A. 25565–67. There is no indication from the record that Dr. Clark relied on the intent aspect of his claim interpretation in reaching his infringement opinion. During his direct testimony, he testified that each of the accused ports were suitable for power injection based on evidence that they were structurally capable of withstanding the pressures and flow rates used during such injections. This testimony did not rest on any conclusion that the devices were intended for such use.

The court erroneously relied on our statement in *Wiener v. NEC Electronics, Inc.* that an expert's infringement

testimony did not "create a factual dispute" where his opinion "rest[ed] on an incorrect claim interpretation." 102 F.3d 534, 542 (Fed. Cir. 1996). In *Wiener*, the expert's doctrine-of-equivalence opinion failed to apply the requirement, as construed on appeal, that certain claimed "columns" be located on the data matrix of the claimed memory chip. *Id.* Without an analysis of that essential requirement, the expert's opinion on the issue of equivalence was merely "conclusory." *Id.* Our decision in *Cordis Corp. v. Boston Scientific Corp.* is similarly distinguishable. 658 F.3d 1347, 1357 (Fed. Cir. 2011). There, we disregarded an infringement expert's testimony that relied on an incorrect understanding of the claim construction because the expert's erroneously broad interpretation ignored a specific requirement of the court's construction. *Id.* Here, even if Dr. Clark assumed that the claims required an additional intent element, nothing in the record suggests that this caused him to disregard the requirements of the asserted claims under the correct construction. Although the mistake might undermine his credibility, it does not make his testimony legally insufficient to support an infringement verdict. The district court thus erred in granting JMOL on this basis.

Second, although Bard did not conduct its own tests of the Xcela port's suitability for power injection, Bard was entitled to rely on AngioDynamics's representations to its customers and to the FDA that the Xcela port was suitable for power injection at the flow rate and pressure required by the claims. *See* J.A. 26640–41, 25300–01. Neither the district court nor AngioDynamics provide any reason for why direct testing evidence is required as a matter of law to establish infringement under these circumstances. AngioDynamics's statements regarding the capabilities of its own product constituted substantial evidence of those capabilities. *See* FED. R. EVID. 801(d)(2). The weight assigned to that evidence was a question for the jury.

Third, even if Bard did not present direct evidence of specific instances in which an entity performed each of the claimed steps of the '478 patent, there was sufficient circumstantial evidence in the record to support AngioDynamics's induced infringement of the method claims. This court held in *Toshiba Corp. v. Imation Corp.* that "where an alleged infringer designs a product for use in an infringing way and instructs users to use the product in an infringing way, there is sufficient evidence for a jury to find direct infringement." 681 F.3d 1358, 1365 (Fed. Cir. 2012). This type of circumstantial evidence is sufficient for a jury to "reasonably conclude that, sometime during the relevant period[,] more likely than not one [entity] somewhere in the United States" performed each of the claim steps, even when there is no direct evidence of a specific person doing so. *Id.* at 1366 (ellipsis omitted, alterations added). Here, Dr. Clark testified that, in his professional experience, (1) the steps of scanning, identifying, and injecting, as required by the asserted method claims, were generally performed by a single CT technician (J.A. 25554–55), and (2) the implantation of the port, as required by claims 9 and 11, were typically performed by another medical provider at the same hospital, who would be acting as part of the same "entity" as the medical providers performing the other claim steps (J.A. 25533, 25539, 25558, 25569–70). Dr. Clark also pointed to instructional materials provided by AngioDynamics that directed medical providers to perform each step of the claimed methods. J.A. 25540; 26660–71, 26783–90, 26803–08, 26820–25. This constituted substantial evidence to support a jury verdict of infringement as to the method claims of the '478 patent. *Id.*

For these reasons, the district court erred in granting JMOL of non-infringement as to each of the asserted claims.

B. Willful Infringement

The district court granted judgment of no willful infringement based on its conclusion that Bard had failed to show infringement. In the alternative, the court held that Bard had failed to meet its burden as to willfulness because AngioDynamics had obtained written opinions of counsel regarding the invalidity of the asserted claims of the patents-in-suit, and Bard had failed to show that the opinions were "drafted by a bad law firm" or put forth other evidence of willfulness. *Bard*, 382 F. Supp. 3d at 335 n.5.[2] This was error.

Bard introduced evidence at trial that AngioDynamics's Director of Intellectual Property was aware of the applications that issued as the patents-in-suit prior to their issuance. J.A. 25505, 25550, 25496. Bard also introduced evidence that AngioDynamics intentionally copied Bard's CT radiographic marker based on market demand. Appellants' Br. 37–38. This is sufficient evidence to support a jury verdict of willfulness. *See Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1377–79 (Fed. Cir. 2020) (discussing list of facts a jury can properly consider in assessing willfulness); *Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1353–54 (Fed. Cir. 2018) (discussing evidence of intentional copying of a competing product as sufficient to support a verdict of willful infringement). While the existence of an invalidity opinion is a relevant factor in determining willfulness, it was not dispositive, and the question of whether AngioDynamics reasonably believed that the asserted claims were invalid was a question of fact for the jury. *See Eko Brands*, 946 F.3d at 1379.

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[2] While the district court stated that AngioDynamics had obtained both invalidity and non-infringement opinions, only invalidity opinions were presented at trial.

C. Printed Matter and Invalidity

We first clarify procedural aspects of the district court's judgment before addressing the merits of validity. In its final order, the district court granted both summary judgment and JMOL that the patents were invalid and patent ineligible, without specifying the statutory grounds for invalidity. J.A. 1–4. At the time the motions were granted, however, AngioDynamics had not yet presented its invalidity case at trial and Bard had not had the opportunity to defend the validity of its asserted claims. The district court's JMOL of invalidity was thus procedurally improper because Rule 50 provides that JMOL against a party is only appropriate once the party "has been fully heard on an issue." FED. R. CIV. P. 50.

For that reason, we consider the merits of the district court's invalidity judgment only as to the grounds on which AngioDynamics moved for summary judgment, and only to the extent we can reasonably read the district court's decision as bearing on those grounds. In addressing the merits of those grounds, we consider the entirety of the evidence presented during summary judgment, not merely the facts presented at trial. Here, AngioDynamics moved for summary judgment of invalidity based on subject matter ineligibility, anticipation, and non-enablement. Because nothing in the district court's decision references or discusses enablement, we review the court's validity judgment only as to eligibility and anticipation, both of which implicate the printed matter doctrine.

We conclude that although the asserted claims contain printed matter that is not functionally related to the remaining elements of the claims, each claim as a whole is patent eligible because none are solely directed to the printed matter. We also conclude that when we assign no patentable weight to the claimed printed matter, material disputes of fact remain as to whether other elements of the claim are novel over the prior art.

1. Printed Matter

This court and its predecessor have long recognized that certain "printed matter" falls outside the scope of patentable subject matter under U.S. patent law. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010) ("This court has generally found printed matter to fall outside the scope of § 101."); *In re Chatfield*, 545 F.2d 152, 157 (CCPA 1976) ("Some inventions, however meritorious, do not constitute patentable subject matter, e.g., printed matter."). While historically "printed matter" referred to claim elements that literally encompassed "printed" material, the doctrine has evolved over time to guard against attempts to monopolize the conveyance of information using any medium. *See Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 890 F.3d 1024, 1032 (Fed. Cir. 2018); *In re Distefano*, 808 F.3d 845, 849 (Fed. Cir. 2015). Today, printed matter encompasses any information claimed for its communicative content, and the doctrine prohibits patenting such printed matter unless it is "functionally related" to its "substrate," which encompasses the structural elements of the claimed invention. *Praxair*, 890 F.3d at 1032; *DiStefano*, 808 F.3d at 848–49.

In evaluating the existence of a functional relationship, we have considered whether the printed matter merely informs people of the claimed information, or whether it instead interacts with the other elements of the claim to create a new functionality in a claimed device or to cause a specific action in a claimed process. Thus, we held in *In re Marco Guldenaar Holding B.V.*, that the markings on dice had no functional relationship to the dice themselves because the markings did not cause the dice to become a "manufacture with new functionality." 911 F.3d 1157, 1161 (Fed. Cir. 2018). We distinguished the dice markings

from the digits printed on a circular band in *Gulack*[3]—where the digits exploited the band's endless nature and made it useful for performing mathematical operations—and from the volumetric indicia on the side of a measuring cup in *Miller*[4]—where the indicia made the cup useful for measuring partial recipes. *Id.* Based on analogous reasoning, we held in *Praxair* that there was a functional relationship between a step of recommending discontinuation of treatment and a step of actually discontinuing treatment because the claim required that the second step be "based on" the first. 890 F.3d at 1035. In contrast, where the discontinuation step was absent from other claims of the same patent, which merely required physicians to "evaluate" the information, we found no functional relationship between the information in the recommendation and the other steps of the claim. *Id.* at 1033–35.

Here, the parties agree that the asserted claims include printed matter. Each claim requires one or more markers "identifying" or "confirming" that the implanted access port is "suitable" either "for flowing fluid at a rate of at least 1 milliliter per second through the access port" or "for accommodating a pressure within the cavity of at least 35 psi," or both. These elements are directed to the content of the information conveyed.

The parties disagree, however, over whether this printed matter is functionally related to the power injectable port, as recited in all the asserted claims, or to the step of performing a power injection, as recited in the method claims. Bard contends that the information conveyed by the markers provides new functionality to the port because it makes the port "self-identifying." We disagree. A conclusion that mere identification of a device's own

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[3] *In re Gulack*, 703 F.2d 1381, 1382–83 (Fed. Cir. 1983).

[4] *In re Miller*, 418 F.2d 1392, 1393 (CCPA 1969).

functionality is sufficient to constitute new functionality for purposes of the printed matter doctrine would eviscerate our established case law that "simply adding new instructions to a known product" does not create a functional relationship. *AstraZeneca*, 633 F.3d at 1065 (citing *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004)). Indeed, as early as the 1930s, our predecessor court recognized that the mere marking of products, such as meat and wooden boards, with information concerning the product, does not create a functional relationship between the printed information and the substrate. *See In re McKee*, 75 F.2d 991, 992 (CCPA 1935); *In re Johns*, 70 F.2d 913, 915 (CCPA 1934); *In re Bruce*, 56 F.2d 673, 674 (CCPA 1932).

Bard also contends that the printed matter is functionally related to the power injection step of the method claims because the medical provider performs the power injection "based on" the identification of the port's functionality. But there is no language in the claims suggesting such a causal relationship. Bard did not advocate for that construction before the district court, and we see no persuasive basis for reading that limitation into the claims. Thus, we hold that the content of the information conveyed by the claimed markers—i.e. that the claimed access ports are suitable for injection at the claimed pressure and flow rate—is printed matter not entitled to patentable weight.

We next consider whether, in light of the claimed printed matter, the district court properly concluded that the asserted claims were invalid as ineligible or anticipated.

2. Subject Matter Eligibility

To determine whether claimed subject matter is patent eligible, we apply the two-step framework set forth in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014). First, at step one, we "determine whether the claims at issue are directed to a patent-ineligible concept," such as an abstract idea. *Id.* at 218. To determine if the claim's

character as a whole is directed to excluded subject matter, we "look at the focus of the claimed advance over the prior art." *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1346 (Fed. Cir. 2019) (quoting *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016)). If we conclude that the claim is directed to a patent-ineligible subject matter, then at step two, we "examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform'" the claimed ineligible subject matter into a patent-eligible application. *Alice*, 573 U.S. at 221 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72, 80 (2012)). "The 'inventive concept' step requires us to look with more specificity at what the claim elements add, in order to determine whether they identify an 'inventive concept' in the application of the ineligible subject matter to which the claim is directed." *Chamberlain*, 935 F.3d at 1348 (quoting *Affinity Labs*, 838 F.3d at 1258).

Although the underlying rationale of the printed matter doctrine lies in the requirements of subject matter eligibility under § 101, our case law has typically applied the doctrine to hold that specific limitations of a claim are not entitled to patentable weight for purposes of novelty under § 102 and non-obviousness under § 103. *See Praxair*, 890 F.3d at 1032 (citing *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010), and *In re Huai-Hung Kao*, 639 F.3d 1057, 1072–74 (Fed. Cir. 2011)). Notably, since the Supreme Court articulated its two-step framework in *Alice*, this court has not directly addressed whether a patent claim as a whole can be deemed patent ineligible on the grounds that it is directed to printed matter at step one and contains no additional inventive concept at step two.

Bard suggests that the answer is no. In support, Bard cites to our decisions in *Miller* and *King Pharmaceuticals*, where we declined to hold that claims covering printed matter were patent ineligible under § 101 and instead

evaluated whether the printed matter elements were entitled to patentable weight for purposes of §§ 102 and 103. But in neither case did we foreclose the possibility that an entire claim could be found patent ineligible when the claim as a whole is directed to printed matter. Rather, in *Miller*, we recognized that "printed matter by itself is not patentable subject matter, because [it is] non-statutory,"[5] and in *King Pharmaceuticals*,[6] we determined that the case was not the right vehicle for a § 101 analysis because the claim was plainly anticipated once the printed matter was set aside. Indeed, eighty years ago, our predecessor court held that "where the printed matter, irrespective of the material upon which it is printed, is the sole feature of alleged novelty, it does not come within the purview of the statute, as it is merely an abstract idea, and, as such, not patentable." *McKee*, 75 F.2d at 992. This is consistent with the post-*Alice* decisions in which we have recognized that the mere conveyance of information that does not improve the functioning of the claimed technology is not patent-eligible subject matter under § 101. *See, e.g.*, *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1338 (Fed. Cir. 2017) (concluding that claims directed to the sending and receiving of information were unpatentable as abstract where the steps did not lead to any "improvement in the *functioning* of the system"); *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016) (holding that claims directed to "a process of gathering and analyzing information of a specified content, then displaying the results, and not any particular assertedly inventive technology for performing those functions" are directed to an abstract idea); *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014) ("Data in its ethereal, non-physical form is simply information that does not fall under any of the categories of eligible subject

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5 *Miller*, 418 F.2d at 1396.

6 *King Pharms.*, 616 F.3d at 1278.

matter under section 101."). We therefore hold that a claim may be found patent ineligible under § 101 on the grounds that it is directed solely to non-functional printed matter and the claim contains no additional inventive concept.

With that understanding, we turn to the claims at issue here. The asserted claims recite an assembly, system, or method for identifying a vascular access port as power injectable using multiple means for conveying the device's functionality, including, specifically, a radiographic marker. When each claim is read as a whole, the focus of the claimed advance is not solely on the content of the information conveyed, but also on the means by which that information is conveyed. In particular, the claimed invention is described in the patents as satisfying a specific need for easy vascular access during CT imaging, and it is the radiographic marker in the claimed invention that makes the claimed port particularly useful for that purpose because the marker allows the implanted device to be readily and reliably identified via x-ray, as used during CT imaging. *See* '417 patent col. 1 l. 7–col. 3 l. 4.

In concluding that the claims could not be directed to the claimed means for identifying functionality, the district court accepted AngioDynamics's assertion that all the claimed forms of identification, including radiographic marking, were routine and conventional in the art, and thus could not constitute the patentable focus of the claims. In defense of that position, AngioDynamics relies on Bard's admission that the use of radiographically identifiable markings on implantable medical devices was known in the prior art, and points to evidence of such use in the prior art, including one vascular port with an x-ray tag that identified the port's flow rate. Appellee's Br. 48–49; J.A. 17958–62. But even if we were to conclude that the sole focus of the claimed advance was the printed matter, AngioDynamics's evidence is not sufficient to establish as a matter of law, at *Alice* step two, that the use of a radiographic marker, in the "ordered combination" of elements

claimed, was not an inventive concept. *BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1347 (Fed. Cir. 2016). Even if the prior art asserted by AngioDynamics demonstrated that it would have been obvious to combine radiographic marking with the other claim elements, that evidence does not establish that radiographic marking was routine and conventional under *Alice* step two.

In concluding that the method claims were patent ineligible, the district court further relied on its conclusion that the method claims contained no more than a recitation of the standards of medical care required after the FDA warned doctors about power injection through vascular access ports. But while the FDA directed medical providers to verify a port's suitability for power injection before using a port for that purpose, it did not require doing so via imaging of a radiographic marker. There is no evidence in the record that such a step was routinely conducted in the prior art.

We therefore hold that the asserted claims are not patent ineligible under § 101 because the claims in their entireties are not solely directed to printed matter.

3. Anticipation

As explained in our discussion of the printed matter doctrine, when evaluating the novelty and non-obviousness of claims, we must assign no patentable weight to the nonfunctional printed matter in the claims, which in this case is the information that the claimed access ports are suitable for injection at the claimed pressure and flow rate. Here, Bard presented largely undisputed evidence that certain prior art ports, and the use of those ports, satisfied most of the remaining elements of the asserted claims, including power injectability and the presence of external identifiers. However, there remained a factual dispute over whether any of the prior art access ports contained a "radiographic marker" or "radiographic feature" as

required by the asserted claims. Although AngioDynamics points to certain features of two prior art ports, the ATP and Port-a-Cath, that may be detectable via x-ray, Bard presented contrary evidence that these features were not radiographically discernible and could not be used to distinguish or identify the device or its functionality. Appellee's Br. 34–35; J.A. 16217, 17945. This conflicting evidence created a genuine dispute of material fact as to the novelty of the asserted claims. Thus, the district court erred to the extent it granted summary judgment of invalidity based on anticipation under § 102.

CONCLUSION

Because there remained triable issues of fact as to the infringement and validity of the asserted claims, the district court erred in not permitting Bard to fully present its case at trial. For the reasons discussed, we reverse-in-part the district court's judgment of invalidity as it pertains to ineligibility under § 101, we vacate-in-part the court's judgment of invalidity as to all other grounds, we vacate the judgment of non-infringement and no willful infringement, and we remand the case for further proceedings consistent with this opinion.

REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

Costs to Appellants.